

**United States Surgical Corporation
510(k) Premarket Notification
AUTO SUTURE* Biopsy Instrument** device**

APR - 5 1996

K 960748

**SUMMARY OF INFORMATION SUPPORTING
SAFETY AND EFFECTIVENESS:**

The AUTO SUTURE* Biopsy Instrument** device is identical in safety and effectiveness to its currently marketed predicate - IMAGYN Medical Inc's biopsy instrument as described in Laparoscopic Instruments - 510(k) #K944129. United States Surgical Corporation has been manufacturing endoscopic hand instruments as accessories in surgical procedures for a number of years. It is now the intention of USSC to manufacture for the marketplace a reusable biopsy instruments identical to that described in IMAGYN's 510(k). The information included in this notification demonstrates that the device is substantially equivalent to its predicate in respect to design, function, performance, labeling and sterilization.

- Both the subject and predicate devices are designed and indicated for the same procedures.
- Both the subject device and other currently marketed United States Surgical Corporation devices are manufactured in the same facilities, using similar processes and controls.
- Both the subject device and other currently marketed United States Surgical Corporation devices are packaged in the same facilities using similar processes and controls.
- Both the subject and predicate devices perform the exact same function in the same way.